IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PHARMASTEM THERAPEUTICS, INC., Plaintiff,	)	
v.	)	Case No. 02-148 GMS
VIACELL, INC., et al., Defendants.	)	

MEMORANDUM

I. INTRODUCTION

On February 22, 2002, PharmaStem Therapeutics, Inc. ("PharmaStem") filed this lawsuit against ViaCell, Inc. ("ViaCell"), Cryo-Cell International, Inc. ("Cryo-Cell"), CorCell, Inc. ("CorCell"), StemCyte, Inc. ("StemCyte"), CBR Systems, Inc. ("CBR"), Birthcells Technology, Inc. ("Birthcells"), Nustem Technologies, Inc. ("Nustem"), and Bio-Cell, Inc. ("Bio-Cell") (collectively, the "defendants")[1], alleging infringement of United States Patents Nos. B1 5,004,681 ("'681 Patent") and 5,192,553 ("'553 Patent"). On October 29, 2003, the jury returned a unanimous verdict on all claims in favor of Pharmastem. The parties then filed several post-trial motions.[2] On September 15, 2004, the court issued a Memorandum Opinion and Order (the "Post-trial Order") addressing the

[1] A default judgment was subsequently rendered against NuStem on July 10, 2002. StemCyte and PharmaStem entered a settlement agreement before trial, and StemCyte accordingly was dismissed from this action on October 21, 2003.

[2] ViaCell filed a renewed motion for judgment as a matter of law, and, in the alternative, a motion for a new trial or for a remittitur, in which the defendants CBR, CorCell, and Cryo-Cell joined. ViaCell filed another alternative motion, in which the other defendants also joined, for findings by the court and or to alter or amend judgment pursuant to Federal Rule of Civil Procedure 52, 59(e) and/or the court's equitable power. PharmaStem filed a motion for enhanced damages, attorneys' fees, pre-judgment interest and post judgment interest, a motion for a permanent injunction, and a motion to strike the affidavit of Chris Adams submitted in support of ViaCell's motion to alter or amend the judgment.

post-trial motions. The court concluded that the defendants do not infringe the '553 patent and granted a partial new trial on the issue of infringement and damages with respect to the '681 Patent.[3]

Following the Post-trial Order, CorCell and Cryo-Cell filed a motion for partial reconsideration of the court's post-trial rulings. CBR and Viacell joined the motion and submitted individual memoranda that addressed issues specific to each of them. In addition, ViaCell filed a motion for entry of separate and final judgment pursuant to Federal Rule of Civil Procedure 54(b) and a motion for certification for interlocutory appeal pursuant to 28 U.S.C. § 1292(b), in which CBR, CorCell, and Cryo-Cell joined. PharmaStem filed a motion for a preliminary injunction, as well as a motion for entry of separate and final judgment pursuant to Federal Rule of Civil Procedure 54(b). For the following reasons, the court will grant the defendants' motion for partial reconsideration, reverse its post-trial ruling as to the '681 patent, and enter judgment as a matter of law ("JMOL") that the defendants do not infringe the '681 patent.[4]

II. STANDARDS OF REVIEW

A. Motion For Reconsideration

As a general rule, motions for reconsideration should be granted only "sparingly." *Tristrata Tech., Inc. v. ICN Pharms., Inc.*, 313 F. Supp. 2d 405, 407 (D. Del. 2004); *Karr v. Castle*, 768 F.

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[3] For a complete recitation of the facts, procedural history, and post-trial rulings of this case, please see *Pharmastem Therapeutics, Inc. v. Viacell, Inc.*, C.A. No. 02-148 GMS, 2004 WL 2127192 (D. Del. Sept. 15, 2004).

[4] The court will deny the plaintiff's and the defendants' motions for entry of separate and final judgment pursuant to Federal Rule of Civil Procedure 54(b), the defendants' motion for certification for interlocutory appeal pursuant to 28 U.S.C. § 1292(b), and the plaintiff's motion for preliminary injunction, because the court's ruling on the motion for reconsideration renders them moot.

Supp. 1087, 1090 (D. Del. 1991). In this district, these types of motions are granted only if it appears that the court has patently misunderstood a party, has made a decision outside the adversarial issues presented by the parties, or has made an error not of reasoning, but of apprehension. *See, e.g.*, *Shering Corp. v. Amgen, Inc.*, 25 F. Supp. 2d 293, 295 (D. Del. 1998); *Brambles USA, Inc. v. Blocker*, 735 F. Supp. 1239, 1240 (D. Del. 1990) (citing *Above the Belt, Inc. v. Mel Bonhannan Roofing, Inc.*, 99 F.R.D. 99 (E.D. Va. 1983)); *see also Karr*, 768 F. Supp. at 1090 (citing same). Moreover, even if the court has committed one of these errors, there is no need to grant a motion for reconsideration if it would not alter the court's initial decision. *See Pirelli Cable Corp. v. Ciena Corp.*, 988 F. Supp. 424, 455 (D. Del. 1998). Finally, motions for reconsideration "should not be used to rehash arguments already briefed." *TI Group Automotive Systems, (North America), Inc. v. VDO North America L.L.C.*, 2002 U.S. Dist. LEXIS 1018, 2002 WL 87472 (D. Del. 2002) (citation omitted); *see also Quaker Alloy Casting v. Gulfco Industries, Inc.*, 123 F.R.D. 282, 288 (N.D. Ill. 1988) ("This Court's opinions are not intended as mere first drafts, subject to revision and reconsideration at a litigant's pleasure.").

B. Renewed Motion for Judgment as a Matter of Law

Pursuant to Federal Rule of Civil Procedure 50, a court may render JMOL after the moving party is fully heard on an issue at trial, if "there is no legally sufficient evidentiary basis for a reasonable jury to find for that party on that issue." *Walter v. Holiday Inns, Inc.*, 985 F.2d 1232, 1238 (3d Cir. 1993) (citation omitted). If the court denies a motion for JMOL during trial, the motion may be renewed within ten days of entry of judgment in the case. FED. R. CIV. P. 50(b). To prevail on a renewed motion for JMOL following a jury trial, a party "must show that the jury's findings, presumed or express, are not supported by substantial evidence or, if they were, that the

legal conclusion(s) implied [by] the jury's verdict cannot in law be supported by those findings.'" *Pannu v. Iolab Corp.*, 155 F.3d 1344, 1348 (Fed. Cir. 1998) (quoting *Perkin-Elmer Corp. v. Computervision Corp.*, 732 F.2d 888, 893 (Fed. Cir. 1984)). "'Substantial' evidence is such relevant evidence from the record taken as a whole as might be accepted by a reasonable mind as adequate to support the finding under review." *Perkin-Elmer Corp.*, 732 F.2d. at 893. In assessing the sufficiency of the evidence, the court must draw all reasonable inferences from the evidence in the light most favorable to the nonmovant. *Id.*; *Richardson-Vicks Inc. v. UpJohn Co.*, 122 F.3d 1476, 1479 (Fed. Cir. 1997). The appropriate inquiry is whether a reasonable jury, given the facts before it, could have arrived at the conclusion it did. *Dawn Equip. Co. v. Kentucky Farms, Inc.*, 140 F.3d 1009, 1014 (Fed. Cir. 1998). The court may not determine the credibility of the witnesses nor "substitute its choice for that of the jury between conflicting elements of the evidence." *Perkin-Elmer Corp.*, 732 F.2d at 893.

III. DISCUSSION

In the Post-trial Order, dated September 15, 2004, the court denied the defendants' motion for JMOL on the issue of infringement and damages with respect to the '681 patent, but granted the defendants' motion in the alternative for a new trial on this issue. By their motion, the defendants request the court to reconsider its Post-trial Order and grant the motion for JMOL.

The defendants contend that Pharmastem failed to meet its burden with respect to infringement of the '681 patent because: (1) the issue before the jury, as Pharmastem chose to try the case, was whether all of the cord blood units processed and cryopreserved by the defendants infringe the '681 patent, and they do not, and (2) Pharmastem was obligated, as a matter of law, to

adduce evidence with respect to specific units of cord blood stored by the defendants and to show with respect to those specific units that they contain sufficient stem cells to reconstitute a human adult, and did not meet this obligation. The defendants rely on the Post-trial order for support.

In response, Pharmastem asserts that it adduced substantial evidence at trial that the defendants infringe the '681 patent. Pharmastem also asserts that the scientific and medical evidence support cord blood transplantation in adults, and that the defendants use that evidence to promote their cord blood banking services for adult use. Pharmastem supports its assertions with statements from the defendants' marketing materials regarding the potential for adult transplantation. Pharmastem also relies on the defendants' testimony regarding their marketing materials, the threshold quantity of cord blood they collect, and the threshold amount of cells they require. Lastly, Pharmastem relies on the Post-trial Order, which states, "[t]he record suggests that at least some of the defendants' cord blood units infringe in that there is evidence of successful transplants of the defendants' compositions into human adults." *Pharmastem Therapeutics, Inc. v. Viacell, Inc.*, C.A. No. 02-148 GMS, 2004 WL 2127192, at *11 (D. Del. Sept. 15, 2004).

The parties agree that the only disputed issue at trial was which of the defendants' cord blood units contain stem cells in an amount sufficient to effect hematopoietic reconstitution of an adult. According to Pharmastem's presentation to the jury, the answer to that issue was 100%. In other words, Pharmastem's position at trial was that "all" of the defendants' cord blood units infringe the '681 patent.[5] Pharmastem's post-trial motions, as well as its motion for preliminary injunction are

[5] Indeed, when referring to question fourteen of the verdict form during closing arguments (*i.e.*, the question that directed the jury to enter the number of cord blood units that infringe the '681 patent), counsel for Pharmastem told the jury to base the number of units that infringe on the numbers provided by the defendants – that is, 34,293 for ViaCell; 49,646 for Cryo-Cell;

unclear as to whether it has changed its position regarding infringement. For example, Pharmastem's opposition to CBR's motion for judgment as a matter of law states that "CBR's admissions in its marketing documents, the standard operating procedures of the company, as well as the testimony of Dr. Harris support a finding that **all** of the samples infringe. . . ." (D.I. 418, at 3). In addition, Pharmastem's opening brief in support of its motion for preliminary injunction defines the issue as follows: "As the Court recognizes, the dispute is not whether any of the defendants' cord blood units infringe, as 'the record suggests that at least some of the defendants' cord blood units infringe . . .', but whether *all (i.e., every single one)* of the defendants' cord blood units infringe." (D.I. 559, at 5) (emphasis added). Pharmastem's opposition brief to the motion for reconsideration, however, states that "[t]here is abundant medical, scientific, and party proof that the vast majority, if not all, of the defendants cord blood units contain stem cells in an amount sufficient to effect hematopoietic reconstitution of an adult." (D.I. 571, at 14). After reviewing the record, the post-trial motions, and the motion for reconsideration, the court concludes that Pharmastem's position, prior to its briefing on the motion for reconsideration, was that 100% of the defendants cord blood units infringe the '681 patent.[6] Therefore, in order to meet its burden, Pharmastem had to adduce evidence that 100% of the defendants' cord blood units contained stem cells in a sufficient amount to reconstitute a human adult. Pharmastem, however, did not meet its burden.

4,640 for CorCell; and 34,649 for CBR. These numbers are equivalent to the total number of cord blood units stored by each of the defendants. Further, Pharmastem did not refer to any specific unit or units in presenting its case to the jury. Rather, Pharmastem referred to the defendants' cord blood units as a whole

[6] The court will hold Pharmastem to its presentation to the jury, as well as its assertions in its post-trial motions and its motion for preliminary injunction.

First, the court has already determined that "the record overwhelmingly indicates that cord blood units will not all contain sufficient cells to reconstitute an adult." *Pharmastem Therapeutics, Inc. v. Viacell, Inc., et al.*, No. C.A. 02-148 GMS, 2004 WL 2127192, at *11 (D. Del. Sept. 15, 2004). For example, the '681 patent illustrates that each cord blood sample will vary in terms of its cell count. '681 patent Table III (providing cord blood samples with different total volumes and total nucleated blood cells). In addition, Pharmastem represented to the PTO that cord blood units "are highly variable in their stem cell content such that any particular cord blood collection may have low or no stem cells." Tr. Ex. 1370, at 30; *see* Wagner Tr. at 1270. The court, therefore, will affirm its post-trial conclusion that "[t]he jury's finding that *all* of the defendants' cord blood units infringe the '681 patent . . . was against the great weight of the evidence." *Pharmastem*, 2004 WL 2127192, at *11.

Second, even assuming that "at least some of the defendants' cord blood units infringe in that there is evidence of successful transplants of the defendants' compositions into human adults," the court finds that Pharmastem presented no evidence to the jury from which it could conclude that any specific cord blood unit or units stored by any of the defendants contained stem cells in a sufficient amount to reconstitute a human adult. All of the defendants made available to Pharmastem their data with respect to individual units. Pharmastem, however, did not have its infringement expert, Dr. Mary Hendrix ("Dr. Hendrix"), testify regarding whether the data indicated that any of the defendants' units infringed. In fact, Dr. Hendrix testified that she did not review the defendants' data. Hendrix Tr. at 1038. Rather, Dr. Hendrix based her infringement opinion on the fact that the defendants "promise stem cells for pediatric and adult transplantation." *Pharmastem*, 2004 WL 2127192, at *11.

In addition, Pharmastem presented no evidence to the court regarding how to quantify the defendants' infringement and damages flowing from the infringement. Instead, Pharmastem chose to offer the evidence of successful adult transplants to prove that 100% of the defendants' units infringe. However, evidence of one successful adult transplant with a single cord blood unit does not prove that any other unit has sufficient stem cells to reconstitute a human adult because, as previously stated, cord blood units are highly variable in their stem cell content. As such, the court will not infer that 100% of the defendants' units infringe based on the defendants' statements regarding adult transplantation. Pharmastem failed to present evidence to the jury from which it could conclude that any specific cord blood unit or units stored by any of the defendants contained stem cells in a sufficient amount to reconstitute a human adult. The court, therefore, cannot determine which or how many of the defendants' units infringe, or how to quantify damages for infringement. Thus, the defendants are entitled to JMOL because there was no legally sufficient evidentiary basis for a reasonable jury to find that all, or any specific number, of the defendants cord blood units infringe the '681 patent.

Dated: December 14, 2004

UNITED STATES DISTRICT JUDGE